

BULLIED, Neil J.  
Appl. No. 10/632,847  
June 11, 2007

### REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

The specification has been amended to include sequence identifiers. The specification has also been amended to include the Sequence Listing submitted herewith on separate sheets. The Sequence Listing submitted herewith differs from that filed December 22, 2004 in that SEQ ID NO:6 has been revised to correct a clerical error noted by the Examiner. Entry of the Sequence Listing does not raise the issue of new matter as the sequence information contained therein is presented in the application as originally filed.

The claims have been revised to define the invention with additional clarity.

Claims 28-37 and 39-43 stand rejected as allegedly representing obviousness-type double patenting over claims 1-3, 5, 6, 12, 13 and 17-19 of Bulleid et al (USP 6,171,827). Withdrawal of the rejection is submitted to be in order for the reasons that follow.

The claims as presented, which are drawn to a production method, require that a first procollagen be produced in a cell that expresses and assembles a second procollagen. No such cell is suggested by the claims of USP 6,171,827. Further, the present claims require the expression in the cell of nucleic acid sequence(s) that encode(s) a pro- $\alpha$  chain for assembly into the first procollagen, which nucleic acid sequence(s) do/does not encode pro- $\alpha$  chain(s) that co-assemble with the pro- $\alpha$  chains that assemble to form the second procollagen. Clearly, nothing in the cited patent claims are suggestive of this further requirement.

In view of the foregoing, it is submitted that withdrawal of the rejection is in order and same is requested.

BULLIED, Neil J.  
Appl. No. 10/632,847  
June 11, 2007

Claim 34 stands rejected under 35 USC 112, first paragraph. Withdrawal of the rejection is submitted to be in order in view of the submission herewith of a Sequence Listing in which the sequence for SEQ ID NO:6 has been revised to correct the clerical error noted by the Examiner. Reconsideration and withdrawal of the rejection are requested in view of the correction.

Claims 28-44 stand rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

At the outset, attention is directed to the fact that the language of claim 28 parallels that of USP 6,171,827 as regards the definitions of the first and second moieties. For that reason alone, the rejection must fail.

Further, Applicant submits that the Examiner is actually incorrect from the standpoint that the Walmsley et al paper does not show that mini-collagens cannot assemble. Indeed, they do and the somewhat isolated sentence to which the Examiner refers, taken out of context, relates to experimental conditions that have been manipulated to prevent secretion of the mini-collagen construct. The remainder of the paper (and, in fact, earlier published work from Applicant's laboratory) demonstrates that this construct does assemble to form triple helical molecules.

The first paper referred to by the Examiner, Myllyharju et al, does demonstrate that one particular construct having an altered C-propeptide does not assemble in insect cells but Applicant submits that no basis exists for extending this observation to all constructs having modified C-propeptides (it is noted that the triple helical domain used in these experiments (the alpha-2 chain from type I collagen) has a low content of hydroxyproline residues).

Additionally, the Examiner is reminded that the present claims are directed to a method of production, not to collagen molecules *per se* (the Examiner is further reminded that the Office found allowable the polypeptides of USP 6,171,827). Applicant submits that the subject

BULLIED, Neil J.  
Appl. No. 10/632,847  
June 11, 2007

disclosure fully enables the claimed production method and that to require limitation of the claims as the Examiner has suggested would be to unduly restrict Applicant in the scope of protection to which he is rightly entitled.

Reconsideration is requested.

Claims 28-44 stand rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

While the Examiner's concerns regarding the definiteness of claims 28 and 37 are not believed to be well founded, the claims have been revised to define the invention with additional clarity. Reconsideration is requested.

Claims 28-32, 37 and 39-43 stand rejected under 35 USC 102(b) and 35 USC 102(e) as allegedly being anticipated by Prockop et al. A similar rejection was raised in parent Application No. 09/380,377 against the claims then pending. On page 10 of the Office Action dated June 24, 2002, the Examiner assigned to the parent acknowledged that the amended claims (corresponding to those presented here) were not anticipated from Prockop et al. Accordingly, reconsideration is requested.

Claims 28-33 and 35-43 stand rejected under 35 USC 102(e) as allegedly being anticipated by Bulleid et al. The rejection is traversed.

The Examiner appears to have overlooked the requirements in the claims relating to the nature of the host cells used and the nucleic acid sequence expressed (see comments above responsive to the rejection based on obviousness-type double patenting). These requirements are not taught by citation.

BULLIED, Neil J.  
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Arguments consistent with those above were presented in the parent case in response to similar rejection raised in the Office Action date May 9, 2001 (see page 9). The rejection was acknowledged as being overcome on page 10 of the Office Action dated June 24, 2002.

Reconsideration is requested.

Claims 28-33 and 35-42 stand rejected under 35 USC 102(f). The rejection is clearly based on the Examiner's misunderstanding of the reference (see comments above).  
Reconsideration is thus requested.

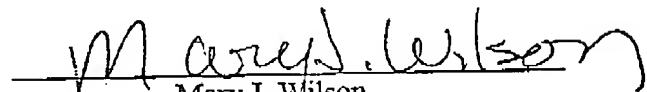
Claims 28-44 stand rejected under 35 USC 103 as allegedly being obvious over Bullied et al as evidenced by Barr et al. Nothing in Barr et al cures the fundamental failings of the primary reference (see comments above). Accordingly, reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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